EXHIBIT 4

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Fleminger Inc

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Dr. Lee
Dba Dr. Lee's TeaForHealth™
Fleminger Inc.
160 Hawley Lane, Suite 205
Trwnbull, CT 06611

CFSAN-OC-10-01

Dear Dr. Lee:

This is to advise you that the Food and Drug Administration (FDA) reviewed your websites on December 8, 2009 at the Internet addresses www.teaforhealth.com and www.greenteahaus.com. The FDA has determined that your TeaForHealth™ green tea products, Dr. Lee's TeaForHealth® 710EGCG™ inabottle™ Green Tea and Tea For Health® 710EGCG™ Ready-To-Drink Natural Brewed Green Tea, are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(I)], new drugs under section 201(P) of the Act [21 USC § 321(P)], and misbranded under sections 403(a)(1), 403(r)(1)(A), 403(r)(1)(B), and 502(f)(1) of the Federal Food, Drug; and Cosmetic Act (the Act) [21 U.S.C. §§ 343(a)(I), 343(r)(1)(A), 343(r)(1)(B), and 352(f)(1)]. The marketing of the products with these claims violates the Act.

I. Unapproved New Drugs:

Your website, www.teaforhealth.com. redirects the consumer to another site of yours, www.greenteahaus.com. that makes several claims and provides links to articles, brochures, and other "educational materials." Examples of the disease claims observed on www.greenteahaus.com include:

- "Produced according to NCI specifications*" and "Green tea of the NCI-defined strength*" where the asterisks lead the consumer to the text: "Based on the pharmacodynamics data published by the National Cancer Institute (NCI)...daily consumption of 1,200 ml (40 ounces) of green tea containing 710 mcg/ml (-)epigallocatechin gallate (EGCG).. .is equivalent to 1.5 times the lowest anticancer effective dose in a 70-kg (154-lb.) person. Up to 10 times the lowest effective dose can be well tolerated by cancer patients if properly administered."
- "[G]reen tea may be also useful in enhancing the anticancer effects of conventional chemotherapeutics (chemo), even synergistically with the less toxic antineoplastic drugs of the quinolone family, and in controlling Alzheimer's disease, Parkinson's disease, obesity, blood thrombosis, cardiovascular diseases, diabetes ... viral infections, liver damage ... and antibiotic-resistant bacterial infections."
- "As a COX-2 inhibitor, green tea may provide some of the benefits that Vioxx and Celebrex had offered to patients without their toxicities."

Examples of disease claims on www.greenteahaus.com in the form of headings of categorized "educational materials" include:

- "[A]nticancer effects of green tea and the EGCG level of the green tea used in cancer research"
- "Green tea or its components may enhance anticancer effects of drugs and prolong cancer patient survival"
- "Neuroprotection of green tea against Alzheimer's disease and Parkinson's disease"
- "Green tea is anti-thrombotic and may help blood circulation"
- "Antiviral effects of green tea"
- "Liver protection of green tea against hepatitis and other injuries"
- "Green tea enhances the antimicrobial effects of antibiotics, especially that against methicillin-resistant strains of staphylococcus aureus, MRSA"

Your website, www.greenteahaus.com. links to the full text of a brochure entitled, "The Truth in Tea." Examples of disease claims in this brochure include:

- "The anticancer activities of green tea or its components, especially the antioxidants, for example, EGCG, are widely ranged, starting at inhibition of the formation of exogenous carcinogens in the stomach to interference with tumor initiation, promotion and progression."
- "The women drinking 10 Japanese cups (1200-1500 ml) or more green tea a day enjoy an average 8.7 more cancer-free years than low volume tea drinkers do ... The result showed a reduction of breast cancer rate in association with drinking green tea and their dose-dependent relationship...."
- "Heavy green tea consumption was found to be associated with reduced recurrence of breast cancer in [Stage I and Stage II breast cancer] patients ... "
- "[G]reen tea... [was] found to enhance the anticancer effects of certain chemotherapeutic drugs, like 5- fluorouracil and doxorubicin. Thus green tea as dietary supplement may reduce the required dosage of certain anticancer drugs and minimize their adverse side effects."
- "Green tea...has been shown to be potentially beneficial in the fight against viral infections through the following mechanisms:
    - o "Antimutagenic at the molecular level - to reduce the chance of virus mutation. Viral mutation has been a big problem in treating SARS and HIV patients."
    - o "Antiviral at the cellular level (inhibit replication of viral particles, e.g., by interfering with HIV attachment to CD4 lymphocytes).
    - o "Boosting the immunity of the human body (an old concept in Chinese medicine, but quite new in western medicine) against viral and bacterial infections."
    - o "Enhancing the antimicrobial activity of the antibiotics against secondary bacterial infections reducing the chance of developing drug resistance and working synergistically with the antibacterial drugs, such as restoring the MRSA sensitivity to methicillin."

These therapeutic claims on your website establish that the products are drugs under section 201(g)(1) of the Act, because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your products are also "new drugs" under section 201 (P) of the Act, because they are not generally recognized as safe and effective for the above referenced conditions. New drugs may not be legally marketed in the U.S. without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. In addition, your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your products are misbranded under section 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for use.

II. Unauthorized Health Claims:

Examples of health claims observed on www.teaforhealth.com include:

- "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."

Examples of health claims on www.greenteahaus.com in the form of headings of categorized "educational materials" include:

- "Epidemiological and clinical studies on the relationship between cancer risk and the consumption of green tea..."

Examples of health claims in "The Truth in Tea" include:

- "[H]igh consumption of green tea [is] associated with reduced cancer rates of the breast, esophagus, stomach, colon, rectum, pancreas, urinary bladder, prostate, lung, liver, and ovary... "
- "Recent medical research has provided evidence that drinking green tea may reduce the risk of fatal heart attack, stroke, Alzheimer's disease, Parkinson's disease, help reduce body fat and help fight viral infection."

These claims cause your products to be misbranded under section 403(r)(1)(B) of the Act in that they are health claims that have not been authorized by regulation or the Act. In a letter issued to you on June 30, 2005 ("the June 2005 letter"), FDA articulated two health claims for green tea for which FDA intended to consider exercising enforcement discretion:

1. "Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer."
2. "One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggest that drinking green tea may reduce this risks. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer."

The claims presented on your websites are not consistent with either of these qualified health claims.

III. Unauthorized Nutrient Content Claims:

Examples of unauthorized nutrient content claims on www.teaforhealth.com include:

- "Drink high antioxidant green tea -- for your health!"

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of

such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g .. asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidan' activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A) of the Act.

Your claim, "Drink high antioxidant green tea," is an unauthorized nutrient content claim. The term "high" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim is unauthorized and causes your product to be misbranded under section 403(r)(2)(A) of the Act.

IV. False or Misleading Labeling:

Your website, www.teaforhealth.com. makes false or misleading statements regarding FDA's conclusions on the relationship between green tea consumption and cancer risk, including:

- "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."
- "Green tea happens to be one of the components in our diet whose anticancer effects have been supported by solid scientific evidence. The consumers are entitled to the whole truth....The fully disclosed accurate language of the [FDA] granted health claims should read as follows (with my clarifying notes added in parentheses):

  1. 'Two studies **(which were conducted among Japanese living in the northern rural Miyagi prefecture where no tea plantations are in existence)** do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study **(which was conducted among green tea drinking Asian women living in Los Angeles, CA, U.S.A.)** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer **(if a green tea similar to those marketed in northern rural Japan is consumed).**'

  2. 'One weak and limited study **(which was conducted among Japanese living in the northernmost island of Hokkaido where no tea trees can survive)** does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study **(which was conducted among the local residents of Hangzhou, the traditional green tea plantation and production capital of China)** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer **(if a green tea similar to those marketed in Hokkaido of Japan is consumed).",*1***

In the June 2005 letter, FDA informed you of the results of our review of the scientific evidence and other information submitted as part of the petition filed under docket 2004Q-0083 regarding green tea and various cancers. We advised you of our conclusions that there is very limited credible evidence for qualified health claims regarding the consumption of green tea and a reduced risk of prostrate cancer and the consumption of green tea and a reduced risk of breast cancer. We also advised you of our conclusion that there is not credible evidence to support a claim with respect to all other types of cancer. The June 2005 letter articulated FDA's intent to consider exercising enforcement discretion for the two qualified health claims cited in section II above.

FDA worded the conclusions and qualified health claims in the June 2005 letter to reflect our careful evaluation and ranking of the level of scientific evidence linking green tea consumption and the risk of various cancers.*2* Your statement, "FDA has concluded that there is credible evidence supporting this claim although the evidence is limited," mischaracterizes FDA's conclusions about the level of evidence suggesting green tea reduces the risk of breast and prostate cancers. Moreover, your edits to FDA's conclusions in the qualified health claims' language and your assertions that your edits make the qualified health claims "fully disclosed" and "accurate" suggest that your rendition of FDA's qualified health claims more accurately reflects and more fully discloses FDA's conclusions than FDA's non-embellished version. These statements alter the meaning of FDA's language and misrepresent FDA's conclusions. Thus, these statements cause your products to be misbranded under section 403(a)(1) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 §§ U.S.C. 332 and 334]. You should take prompt action to

correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include each step that has been or will be taken to completely correct the labeling violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that the correction has been achieved. If applicable, please include a copy of your revised label. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Felicia B. Williams, Compliance Officer, Division of Enforcement, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,
/S/

Roberta Wagner
Director
Office of Compliance
Center for Food Safety and
Applied Nutrition

cc: New England District

---

1 http://www.teaforhealth.comIPR/2006/082806.htm

2 For more information on this process generally, see FOOD & DRUG ADMIN., *Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data* (July 2003), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/03N-0069-gdl0001.pdf.

Links on this page:

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- For Government
- For Press

- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness